Nilotinib

Nilotinib is a targeted treatment used for some people with chronic myeloid leukaemia (CML).

Summary

- Nilotinib is a type of medicine called a tyrosine kinase inhibitor (TKI).
- It comes as hard capsules that you take every day. The number of capsules you need to take should be printed on the named label on the medicine packaging.
- You will have regular blood tests to check how well your CML is responding to nilotinib.
- Your haematology team will also carry out tests to check how your body is coping with nilotinib treatment.
- Side effects of nilotinib are usually mild to moderate. Some people have very few side effects, whereas other people experience more serious side effects.
- Some side effects can be serious if they are not treated promptly. Contact your haematology team straight away if you get:
    - Fainting, palpitations or an irregular heart beat
    - Muscle weakness or fits (seizures)
    - Chest pain or breathlessness
    - Numbness, paralysis or speech difficulty
    - A cold, pale, painful limb
    - Unexpected, rapid weight gain or swelling in your most of your body
- Tell your haematology team if you get any other side effects. They may be able to suggest things to help.

Do not stop taking nilotinib without discussing it with your haematology team.

Download our leaflet about nilotinib

About nilotinib

Nilotinib is a type of medicine called a tyrosine kinase inhibitor (TKI). It blocks an abnormal protein called BCR-ABL, which is a type of tyrosine kinase. This abnormal protein is present in people with CML. It encourages the blood-forming cells in your bone marrow to make too many white blood cells. Blocking the protein helps stop the leukaemia cells from multiplying.

The brand name for nilotinib is Tasigna.

Nilotinib is a common treatment for CML. It is suitable for adults and children. Your haematology team might recommend it for you if:

- You have just been diagnosed with chronic phase CML
- You have chronic phase or accelerated phase CML and previous treatment, including imatinib, either:
    - Did not work
    - Stopped working
    - Caused side effects that were difficult to cope with

Nilotinib is not licensed to treat blast phase CML in children.

Back to top

Before taking nilotinib

Before starting your course of nilotinib, your haematology team will carry out checks to make sure it's suitable for you. These include:

- Checks of your heart health, like taking your pulse and blood pressure measurements, and an electrocardiogram (ECG). Nilotinib can cause changes to your heart rhythm so it may not be suitable if you have heart problems.
- Blood tests to measure the level of fats and sugars in your blood.
- Blood tests to measure the level of potassium and magnesium in your blood. Low levels could make you more likely to have problems with your heart rhythm during nilotinib treatment, so they must be corrected before you start treatment.
- Blood tests to check for viruses like HIV or hepatitis B. Nilotinib can reactivate hepatitis B infection, so if you have it you may need to take an antiviral treatment to prevent this.

They will also check to see if you have any medical conditions such as diabetes, lung conditions or liver problems.

Back to top

How to take nilotinib

Nilotinib comes as hard capsules containing 50mg, 150mg or 200mg of nilotinib. The number of capsules you need to take depends on the dose and strength of the capsule. This should be printed on the named label on the medicine packaging. If you are not sure, ask your doctor or nurse.

- You should take nilotinib twice a day as prescribed so it can work as well as possible. Try to take each dose around 12 hours apart at the same time every day if you can.
- Do not take nilotinib with food because this increases how much of it your body absorbs. This could lead to serious side effects.
    - Wait at least 2 hours after eating before taking nilotinib.
    - Do not eat for at least 1 hour after taking nilotinib.
    - Avoid grapefruit or grapefruit juice because this can increase the effect of nilotinib.

- If you cannot swallow capsules, sprinkle the content of each capsule into one teaspoon of apple sauce. Take the mixture straight away.
- If you forget to take nilotinib, skip your missed dose and then take your next dose as usual. It is important not to take a double dose.

Dose

Most adults with CML take 300mg nilotinib twice daily. Your haematology team may suggest a higher or lower dose, depending on your circumstances. They will tell you what dose they recommend for you.

- People over 65 can usually take the same dose as other people with CML.
- People with liver, kidney or heart problems usually start on the same dose as other people, if nilotinib is suitable for them.
- Doses for children are worked out individually based on their size.

Back to top

Precautions

Some medicines may interact with nilotinib. It is important to tell your haematology team about any medicines or supplements you are taking. This includes prescribed medicines and medicines you have bought yourself without a prescription. Examples include:

- Medicines used to treat abnormal heart rhythms
- Medicines that may have a side effect of changing your heart rhythm
- Medicines that lower your cholesterol level (statins)
- Some medicines used to treat infections
- Some medicines used to treat epilepsy
- Some antihistamines
- Some medicines to prevent blood clots, like warfarin
- Some medicines used to treat schizophrenia or dementia
- Some medicines used during surgery or medical procedures
- Some medicines used to prevent rejection after an organ transplant
- Antacids and other medicines that reduce stomach acid, such as cimetidine, famotidine and nizatidine
- Herbal medicines such as St John’s Wort
- Grapefruit or grapefruit juice

> **Tell your haematology team if you start any new medicines or supplements when you are taking nilotinib.**

Back to top

Pregnancy and breastfeeding

Nilotinib may harm unborn babies.

- If you could get pregnant, it’s important to use effective contraception while taking nilotinib and for up to 2 weeks after you stop.
- If you’re taking nilotinib and you think you might be pregnant, tell your haematology team as soon as possible. They will talk to you about your treatment

options. They may recommend stopping treatment for a while or switching to a different treatment.
- If you are planning to get pregnant in the future, talk to your haematology team who will discuss treatment options with you.

Breastfeeding

Nilotinib passes into breastmilk. We do not know what effect this has on breastfed babies or children. You should not breastfeed while you are taking nilotinib.

Back to top

Monitoring

During your treatment with nilotinib, you will have regular tests to check how well your CML is responding to treatment. These will usually be blood tests and sometimes bone marrow tests.

You are likely to have blood tests every 2 weeks at first. If nilotinib is working well for you, this might reduce to every month.

Monitoring your response to treatment

Tests to monitor how well your CML is responding to nilotinib look at:

- Your blood cell counts.
- The level of the BCR-ABL1 fusion gene in your white blood cells. This is called ‘molecular response’.

Your haematology team will use the results of these tests to check how well nilotinib is working for you.

What your molecular response means

Molecular response is the most sensitive and accurate measure of response. It is measured using a blood test called PCR.

There are different levels of molecular response (MR):

- MR1: Less than 1 in 10 white blood cells (10%) has the *BCR-ABL1* fusion gene. If nilotinib is working well, you should reach MR1 within 3 months of starting treatment.

- MR2: Less than 1 in 100 white blood cells (1%) has the *BCR-ABL1* fusion gene. If nilotinib is working well, you should reach MR2 within 6 months of starting treatment.
- MR3: Less than 1 in 1,000 white blood cells (0.1%) has the *BCR-ABL1* fusion gene. This is sometimes called a **major molecular response** (MMR). If nilotinib is working well, you should reach MR3 within 12 months of starting treatment.
- MR4: Less than 1 in 10,000 white blood cells (0.01%) has the *BCR-ABL1* fusion gene. This is sometimes called a **deep molecular response** (DMR). If you reach and maintain a DMR, you might eventually be able to stop treatment.
- MR5: Less than 1 in 100,000 white blood cells (0.001%) has the *BCR-ABL1* fusion gene. This is also called a **deep molecular response** (DMR). If you reach and maintain a deep molecular response, you might eventually be able to stop treatment.
- Levels below MR5 cannot usually be detected. This is called a **complete molecular response**.

If your *BCR-ABL1* levels have dropped, but you haven't quite met the required targets, you may be in a 'warning' category. You should discuss your options with your haematologist.

Your molecular response can be used to detect any difficulties in treatment early on. It is an essential part of safe monitoring if you can stop treatment.

Monitoring your body's response to nilotinib

Your haematology team will also check how well your body is coping with nilotinib treatment. This might include:

- Blood tests to check how well your liver, kidneys, pancreas, thyroid and bone marrow are working.
    - If these show problems with your bone marrow, you may need to stop taking nilotinib for a while or try a lower dose.
- Blood pressure checks. Nilotinib can increase your blood pressure. If this happens, your doctor might prescribe blood pressure medications. If your blood pressure is very high, you may need to stop taking nilotinib for a while.
- ECG checks and blood tests to check your heart health.
- Blood tests to check your blood sugar and fat levels.

Long term follow-up

Once you have reached a response to treatment, your haematology team will make a follow-up care plan for you. You will have regular appointments to check for any complications or signs you may have lost your response to treatment.

> "I accept I'll be having blood tests and taking medication for the rest of my life but while this disease is part of my life and always will be, I won't let it define me."
>
> — *Marisa, diagnosed with CML at 18*

It is important to go to your follow-up appointments. This is so your team can check how well your treatment is working and how your body is coping. You may have blood tests every few months, and occasionally a bone marrow test, if you have lost response.

Your follow-up appointments will continue in the long term. How often you have appointments will depend on your individual needs - for example, any support you need to manage ongoing side effects.

Back to top

How long to take nilotinib

Most people carry on taking nilotinib for as long as it is working. Your haematology team may suggest stopping nilotinib and trying a different treatment if:

- It is not working well
- It stops working
- You are having side effects that are difficult to cope with

Your haematology team might also discuss reducing your dose, or stopping treatment completely.

Reducing your nilotinib dose

Your haematology team might suggest reducing your dose of nilotinib if you are getting difficult side effects or you are in a major molecular response.

Your haematology team will monitor your treatment response closely after reducing your dose. If you lose your response, they might slowly increase the dose until you reach a response again. The aim is to find the lowest dose that works for you. This keeps your risk of side effects as low as possible.

Stopping nilotinib

Do not stop taking nilotinib without discussing it with your haematology team.

Your haematology team might discuss stopping nilotinib completely if:

- You have been taking it for at least 3 years (ideally 5 years) **AND**
- Your CML has been in deep molecular response (MR4 or MR5) for at least 2 years

This is called treatment-free remission. Your haematology team will talk to you about the benefits and risks of treatment-free remission, so you can decide if it's something you would like to try.

We have separate information about treatment-free remission.

Back to top

Side effects

You may get some side effects while you are taking nilotinib. For most people, these side effects are usually mild to moderate. They may differ from day to day. Some people have very few side effects, whereas other people experience more serious side effects.

The possible side effects of nilotinib are very similar to those with other TKIs. Some are more common, and some less common. Most people with CML need to take one of the TKIs. Your haematology team should tell you about the likelihood of key side effects with different medications.

If you are getting side effects that are difficult to cope with, your haematology team might suggest reducing your dose of nilotinib. They may then try slowly increasing it to find a dose that works for you.

> **Tell your haematology team if you get any side effects. They may be able to adjust your dose of nilotinib, prescribe medicines to help, or suggest things to help you cope.**

Back to top

Serious side effects

> **The following side effects may be serious and require urgent assessment. Contact your doctor straight away if you have any of these side effects.**

- Fainting, palpitations or an irregular heart beat. You may have developed an abnormal heart rhythm. The checks you have before and during nilotinib treatment reduce the risk of this, but it can still happen.
- Sickness, tummy pain, muscle cramps, weeing less than usual, blood in your wee, palpitations or fits (seizures). These could be symptoms of a condition called tumour lysis syndrome. It affects less than 1 in every 1,000 people who take nilotinib, but it can happen if nilotinib makes your cancer cells break down too quickly. This leads to a build up of chemicals in your bloodstream. It needs urgent treatment. Your haematology team will make sure you are not dehydrated before you start treatment, to reduce the risk of this happening.
- Chest pain, breathlessness, numbness or paralysis, speech difficulty or a cold, pale, painful limb. This is because nilotinib can cause serious problems with your circulation, which need to be treated urgently. The checks you have before and during nilotinib treatment reduce the risk of this, but it can still happen.
- Unexpected, rapid weight gain or swelling in your most of your body. This is because nilotinib can cause your body to retain water. Medicines called diuretics can help treat water retention.
- Any other unusual or worrying symptom.

Back to top

Very common side effects

Very common side effects affect more than 10 in every 100 people who are taking nilotinib.

Very common side effects include:

- Rash – if this affects you badly, your doctor might prescribe steroid cream
- Cough, sore throat, runny nose or upper airway infections
- Headache
- Muscle, joint or back pain
- Fatigue or lack of energy
- Feeling or being sick
- Itching
- Unexpected bruising or bleeding like nosebleeds, bleeding gums, blood spots or rashes, due to low platelet levels
- Diarrhoea – if this affects you badly, your doctor might prescribe antidiarrhoeal medicine
- Constipation
- Feeling very tired or short of breath due to low red blood cells (anaemia)
- Tummy pain
- Hair loss
- High temperature
- Slow growth in children
- Changes in the way your liver or pancreas work (found on blood tests)

This is not a full list of all the side effects that can happen. The patient information leaflet has more information.

If you are worried about any side effects or symptoms you have, contact your haematology team.

Back to top

Common side effects

Common side effects affect more than 1 but less than 10 out of every 100 people who are taking nilotinib.

Common side effects include:

- Infections. This may be due to a low white blood cell count, which means you can't fight infections as well as usual. If you get an infection, you need prompt treatment. Signs of infection include:
  - High temperature over 37.5°C or severe chills
  - Sore throat
  - Cough
  - Pain when you wee or weeing more often than usual
  - Diarrhoea
  - Thrush
- Depression or anxiety
- Difficulty sleeping
- Dizziness
- Migraine
- Pins and needles
- Dry, sore, red or inflamed eyes
- Blurred vision
- Ear pain or ringing in the ears
- Feeling short of breath
- Tummy pain, indigestion, bloating or wind
- Piles
- Sores or cracks in the corners of your mouth
- Sweating more than usual or night sweats
- Flushing
- Sore, dry, itchy or inflamed skin
- Spots
- Muscle weakness
- Pain when you wee
- Heavy periods
- Difficult getting or keeping an erection
- Chills or flu-like symptoms

- Feeling generally unwell
- Underactive thyroid gland
- Imbalance in mineral levels in your blood
- Changes in the levels of sugar and fats in your blood
- High blood pressure

This is not a full list of all the side effects that can happen. The patient information leaflet has more information.

> **If you are worried about any side effects or symptoms you have, contact your haematology team.**

Back to top

If nilotinib does not work

If nilotinib hasn't worked, or has stopped working for you, there are lots of other options. These include:

- Increasing the dose of nilotinib you are taking.
- A different TKI. All TKIs work in slightly different ways. If your CML does not respond to nilotinib, it might still respond to a different one. Some people try several different TKIs.
- A stem cell transplant using donor cells. This is called an allogeneic stem cell transplant.

Your haematology team will tell you which option they recommend for you.

We have separate information about:

- Second- and later-line treatments for CML
- Stem cell transplants

Back to top

Need support?

You are not alone. We're here for you whether you have a diagnosis yourself or know someone who has. If you'd like advice, support, or a listening ear, call our freephone helpline on 08088 010 444 or send a WhatsApp message to 07500 068 065.

Helpline and WhatsApp →

Help us improve our information

We aim to provide information that's reliable, up-to-date, and covers what matters to you. Please complete our short survey to help us improve our information and make sure it meets your needs.

Complete our short survey →

About our information

This information is aimed at people in the UK. We do our best to make sure it is accurate and up to date but it should not replace advice from your health professional. Find out more about our information.

Page last reviewed: 30 April 2024
Updated February 2026
Next review due: 30 April 2027

Trusted Information Creator
Patient Information Forum